

REMARKS

Reexamination and reconsideration in light of the foregoing amendments and the following remarks is respectfully requested.

Applicants note the Examiner's acceptance and entry of the Substitute Declaration and Power of Attorney filed November 4, 2002. Applicants further note the Examiner's acknowledgment of Applicants' claim for foreign priority under 35 U.S.C. § 119 and receipt of the certified priority document.

Applicants note that the Examiner did not consider the list of references cited in the Information Disclosure Statement because copies of the references were not submitted. A Supplemental Information Disclosure Statement has been filed to supply the missing references. Consideration of the references in the Supplemental Statement is respectfully requested.

The Examiner objected to portions of pages 3-8, 12, 13 and 15 the specification because of numerous informalities. Each of the formalities has been corrected. The corrections are shown in subsection entitled "Amendments to the Specification," *supra*, which is part of this response. It is believed that all of the informalities identified by the Examiner have been corrected.

In addition, the amendments seek to correct typographical errors in Tables I and IV of the specification. In column 4 (I_{max}) of Table I, in the second section below the heading, the first value should read $--1.34 \pm 0.03--$, and not " $134 \pm 0.03.$ " Also, in column 7 (DL) of Table I, in the third section below the heading, the second value "0.70" should be $--0.07--$. Entry of these amendments is respectfully requested since they are obvious typographical errors when viewed in context with the remaining data in the Table. See also, I_{max} for Type 1 electrode, "Histamine," in Table II on

page 11 of the specification. As for the error in Table IV on page 13 of the specification, the phrase "AO+OV1₁₃-dmeOs" should be --AO+PV1₁₃-dmeOs--. Entry of this amendment is respectfully requested since the error is an obvious typographical error when taken in light of the disclosure at page 13, line 2.

The Examiner objected to claims 5 and 6 because of informalities. These claims have been canceled, thereby rendering the objection moot.

Claims 13-22 are pending in this application. Claims 1-12 have been canceled without prejudice or disclaimer. New claims 13-22 have been added. No new matter has been added to the application. Support for the amendments can be found in the original claims, in the specification at pages 3-9, and in Figs. 1 and 2.

Claims 1, 6, 8, and 10-12¹ stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite on several grounds. The claims have been canceled, thereby rendering the rejection moot.

Claims 10-12 stand rejected under 35 U.S.C. § 101 "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process" The claims have been canceled, thereby rendering the rejection moot.

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Heller et al. (WO 199323748) in view of Ohashi et al. (U.S. Patent No. 5,565,329). Claims 1-10 have been canceled, thereby rendering the rejection moot.

¹ Claim 12 was not included in the statement of the rejection in paragraph 8 of the Office Action. However, in view of the statement regarding the indefiniteness of claim 12 made in paragraph 11 of the Office Action, it is assumed that claim 12 should have been included in the claims rejected in the statement of the rejection in paragraph 8.

Claim 1 has been represented as claim 13 and claims 10-12 have been represented as claims 20-22. Dependent claims 2, 3 and 5-7 have been rewritten as new claims 14-18, which are ultimately dependent on base claim 13. New claims 13, 18 and 20-22 do not include the language objected to by the Examiner in claims 1, 6, 8 and 10-12. For the following reasons, it is believed that new claims 13-22 are patentable over the combined teachings of Heller et al. and Ohashi et al.

The Examiner concedes that Heller et al. "does not teach the use of grass pea-derived, copper-containing amine oxidase or the use of the biosensor for determining freshness of food by detecting the biomarkers." The Heller et al reference relates to an electrode for the detection of hydrogen peroxide wherein the electrode comprises an electrode having a testing surface. On the surface is a transducing film. The film comprises a cross-linked redox polymer network comprising a redox compound having multiple redox centers and a peroxidase. Heller et al. teach that a peroxidase and a second enzyme present are isolated from each other, whereas, in accordance with the biosensors according to the present invention, an amine oxidase is coupled to a peroxidase, i.e. the two enzymes are not isolated from each other. See page 3, lines 6-11 of Applicants' specification). Accordingly, from the teachings of Heller et al., it cannot be concluded that an electrode having the construction as defined in claim 13, can give a very sensible and selective detection/determination of biomarkers in the form of biogenic amines.

The Examiner relies on Ohashi et al. to make up for the deficiencies of Heller et al. In particular, the Examiner made a finding that Ohashi et al. teaches [sic, teach] that the amine histamine is found in foods such as fish and meat that are contaminated" and that an "analyzer is

... disclosed for the detection of histamine to determine freshness of food." The Examiner made a further finding that the analyzer "utilizes an enzymatic reagent having specifically strong oxidase activity to histamine" and that the "enzyme used is a copper-containing amine oxidase (EC 1.4.3.6) extracted from *Aspergillus niger*" From these findings, the Examiner concluded that "[o]ne of ordinary skill in the art would have been motivated to modify the biosensor as taught by Heller et al. by substituting the oxidase into a copper-containing amine oxidase (EC 1.4.3.6) because copper-containing amine oxidases (EC 1.4.3.6) are useful in determining freshness of foods due to the enzyme's strong reactivity to histamine." While the Primary Examiner recognized the claims recited that "the amine oxidase is derived from grass pea," he concluded that "one could have easily substituted this with an enzyme derived from *Aspergillus niger* or another organism because irrespective of the source, all enzymes in EC 1.4.3.6 (copper-containing amine oxidases) would have the same results because these enzymes have the same reaction mechanism." Applicants take exception to the conclusion of the Examiner.

Ohashi et al. is discussed on page 2 of the present specification. It is evident from the discussion that the prior art method disclosed by Ohashi et al. reads on a reduction in dissolved oxygen (DO) and that said method is neither very selective nor sensitive. Ohashi et al. use a copper-containing amine oxidase extracted from *Aspergillus niger*, whereas according to the present invention as set forth in new claim 13 and in all of the claims dependent thereon, an amine oxidase from grass pea is used. The Examiner asserts that all enzymes in EC 1.4.3.6 would have the same results because these enzymes have the same reaction mechanism. However, it is respectfully submitted that this is not true since grass pea amine oxidase exhibits a

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higher sensitivity than other amine oxidases due to the fact that it, unlike other amine oxidases of this type, contains topa-quinone.

For the foregoing reasons, it is submitted that new claims 13-22 are patentable over the combined teachings of Heller et al. and Ohashi et al. Accordingly, favorable reconsideration of the claims is requested in light of the preceding amendments and remarks. Allowance of the claims is courteously solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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